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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,733	07/20/2001	Leo Martis	DI-4389 DIV	2820

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,733	Applicant(s) MARTIS ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8 and 19-31* is/are pending in the application.

4a) Of the above claim(s) *19-22,24-26 and 28-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8,23 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to the directives of paper No. 8 (filed 6/26/02), claim 2 has been amended. Claims 2-8 and 19-31 remain pending. Claims 19-22, 24-26, 28-31 remain withdrawn from consideration, however. Applicants have traversed this restriction. Applicants have argued that claim 19 includes the possibility of having two different solutions. This is entirely true. But the point made in the previous Office action is that claim 19 does not require that there be two different solutions. Claim 19 enocmpasses the possibility of having just one solution in which peptides (2.5 - 40 g/liter) and glucose are present. In addition, as indicated previously, claim 19 imposes no limits on the quantity of glucose that is present. Claim 19 would include a solution that contains glucose that is present at the picomolar level; and claim 19 would include, in the "first part", a saturated solution of glucose. Claim 19 does not actually require that any mixing take place, and claim 19 does not actually require that the solution or solutions be used for dialysis at all. Notwithstanding the foregoing, claims 23 and 27 are now rejoined with the elected group.

Applicants' arguments filed 6/26/02 have been considered and found not persuasive.

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Claims 2-8, 23, 27 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 8, it is recited that the peptides are "approximately 2" amino acids in length. What is meant by this. Does this, or does this not encompass "polypeptides" that are "one" amino acid long?

- Each of claims 23 and 27 is dependent on a non-elected claim.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 2-8 are rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609).

Okamoto discloses (e.g., col 12, lines 66-67) a peritoneal dialysis solution in which the glucose is present to the extent of 0.005 - 78 g/liter, and the pH is 5.5-6.5. The reference

does not suggest that the solution be present in a container which is in proximity to a second container which contains a peptide solution.

Klein teaches (e.g., col 4, line 21+) compositions comprising peptides for peritoneal dialysis. In addition, the reference teaches (col 12, line 40+) that the peptides can be "combined with any osmotically balanced aqueous solution [that is] appropriate...". Klein also does not teach that the peptide solutions should be present in a container which is in proximity to a second container which contains glucose.

Applicants have pointed to example 2 of the specification. In this example, it is argued that if whey protein hydrolyzate is injected intradermally, an allergic reaction ensues. It is also asserted (page 21, last line of text) that the experiments on the whey protein hydrolyzate demonstrate that the peptide mixture of Klein is not clinically acceptable for dialysis. First, the "Klein" document in question is not identified, but even if it is the same as that disclosed in USP 5,039,609, there is no experimental basis for the assertion on page 21, last line of text. This is because the peptide mixtures disclosed by Klein are quite different from whey protein hydrolyzate *per se*. Thus, example 2 is not relevant to this ground of rejection. Applicants have also argued that use of the combination of glucose and peptides permits a lower quantity of peptides to be used, and that administration of peptides in dialysis can cause uremia. While the possibility of such uremia has been suggested in the prior art as a drawback in the use of amino acids *per se*, applicants have

presented no evidence that uremia will occur when peptides are administered. Furthermore, the claims are drawn to compositions, not to methods of use. There is nothing to preclude the possibility of the compositions being used for occasional dialysis, or for dialysis over a short period of time such that uremia would not develop in any case. Applicants have also argued that by selecting a molecular weight within the range of 400-900 D, immunogenicity is minimized. However, Klein discloses (e.g., col 5, line 22+) a preferred weight range of 250-750 D. Accordingly, whatever immunogenicity is obtained (or avoided) should be about the same for the two respective solutions.

Applicants have also argued that no more than 25% of the peptides should have a molecular weight less than 400. However, even if applicants are correct that claim 6 is distinguished on this basis, that arguement is irrelevant in the case of the remaining claims.

As indicated previously, none of claims 2 or 4-8 requires that the two solutions be used on the same patient, or that their use be recommended by the same physician. In response to this, applicants have argued that an intended use limitation somehow distinguishes two solutions that are intended to be combined from two solutions that are not intended to be combined. Suppose that one has one bag containing glucose, and a second bag containing a peptide solution. Both of these bags are connected to the same stand (bearing at least two hooks), such as one commonly sees in hospitals. If applicants were to view these two bags, how would they distinguish two bags which are intended to be mixed, versus two bags

which are not intended to be mixed? To take another example, suppose that a chemist wants to carry out a reaction of the following form:

$$A + B \rightarrow C$$

As it happens, the chemist is located in New York, compound "A" is sold by a chemical company in Missouri, and compound "B" is sold by a chemical company in California. So the chemist places orders for compounds "A" and "B", and a week later carries out the reaction. The question is, if applicants were to inspect the warehouses in Missouri and in California where the chemicals are stored, could they determine whether or not compound "A" was intended to be combined with compound "B"...? Or to take a simple example from everyday life, suppose that on a table in someone's kitchen, there two ceramic (or metal) containers, one of which contains hot coffee, and the other of which contains hot cocoa. Bearing in mind that some people like to mix coffee with cocoa, could applicants determine, by inspecting the two containers, whether or not they were intended to be combined? This intended use issue pertains to all of the claims, with the possible exception of claim 3.

Essentially, applicants have argued limitations that are not in all of the claims, and have argued that example 2 is somehow relevant to Klein. Applicants are incorrect on both of these points. The rejection is maintained.

Thus, the claim is rendered obvious.

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Claims 2-3 are rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609), further in view of either of the following: (a) Loretti (USP 4,997,083) or (b) Larkin (USP 4,608,043).

As indicated previously, Okamoto discloses (e.g., col 12, lines 66-67) a peritoneal dialysis solution in which the glucose is present to the extent of 0.005 - 78 g/liter, and the pH is 5.5-6.5. Also as indicated previously, Klein teaches (e.g., col 4, line 21+) compositions comprising peptides for peritoneal dialysis. In addition, the reference teaches (col 12, line 40+) that the peptides can be "combined with any osmotically balanced aqueous solution [that is] appropriate...".

Loretti and Larkin both disclose sterile containers which comprise two different chambers for mixing solutions. Loretti also suggests (col 1, lines 14-24) that one compartment could house glucose, and the other amino acids. Neither of Loretti or Larkin disclose the specific solutions recited in instant claim 2.

It would have been obvious to combine the solutions of Okamoto and of Klein for additive effects, using the apparatus of Loretti or of Larkin.

*

Claims 2-8 are rejected under 35 U.S.C. §103 as being unpatentable over Klein USP (5,039,609) in view of Faict (USP 5092838)

The teachings of Klein were indicated previously. In addition, Klein discloses (col 3, line 64+) that peptides provide an advantage over amino acids. Faict discloses (col 5, line 15-14) a two part dialysis mixture containing glucose in one part, and histidine, or oligomers thereof, in another. The reference does not explicitly teach the use of peptides in the range of 5-80 g/liter. Thus, it would have been obvious to substitute the peptides of Klein for the amino acids of Faict in order to obtain the advantages disclosed in Klein.

*

Claims 2-3 are rejected under 35 U.S.C. §103 as being unpatentable over Klein USP (5,039,609) in view of Faict (USP 5092838) further in view of either of the following: (a) Loretti (USP 4,997,083) or (b) Larkin (USP 4,608,043)

The teachings of Faict are indicated above; the teachings of Klein were indicated previously. As indicated above, Loretti and Larkin both disclose sterile containers which comprise two different chambers for mixing solutions. Loretti also suggests (col 1, lines 14-24) that one compartment house glucose, and the other amino acids. Neither of Loretti or Larkin disclose the specific solutions recited in instant claim 2.

It would have been obvious to combine the solutions of Faict and of Klein for additive effects, using the apparatus of Loretti or of Larkin.

*

Claims 2-8 are are rejected under 35 U.S.C. §103 as being unpatentable over Klein (U.S.

Patent 5,039,609) in view of Steudle (U.S. Patent 5,011,826).

As indicated, Klein teaches that peptides can be used in a dialysis solution. Also disclosed (col 12, line 40+) is that the peptides can be combined with another "osmotically balanced aqueous solution...". Klein does not single out glucose for this purpose. Steudle teaches (col 4, lines 51-59) that glucose can be combined with peptides in a peritoneal dialysis solution. Applicants have argued that hindsight is required to combine the references. However, Steudle does suggest the combination of glucose and peptides (together with galactose); the medical practioner would have been motivated to select the peptide mixture disclosed by Klein to obtain the advantages asserted therein.

The rejection is maintained.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800